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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,950	05/10/2007	Wesley Blackaby	21573YP	5436
210	7590	11/17/2008	EXAMINER	
MERCK AND CO., INC			RICCI, CRAIG D	
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RAHWAY, NJ 07065-0907			PAPER NUMBER	
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			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,950	Applicant(s) BLACKABY ET AL.	
	Examiner CRAIG RICCI	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

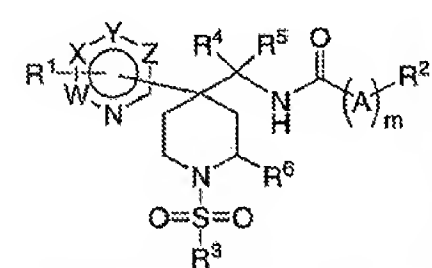
Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

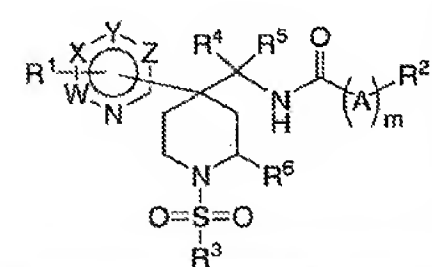
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 18-20 and 22-23, drawn to compounds of formula I



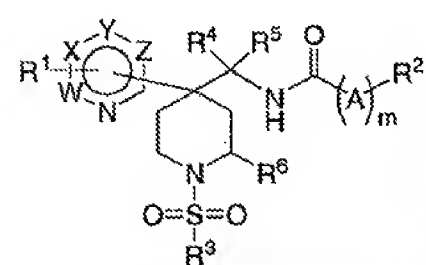
wherein m is zero **and** R² is selected from the group consisting of (1), (2) or (4) as recited by instant claim 1 **and** R³ is selected from the group consisting of (1) as recited by instant claim 1.

Group II, claim(s) 1-14, 18 and 21-23, drawn to compounds of formula (I)

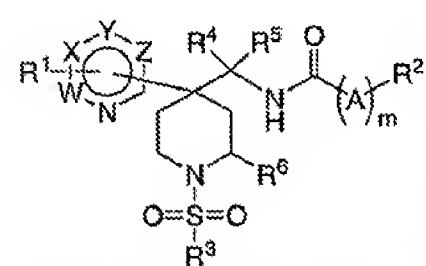
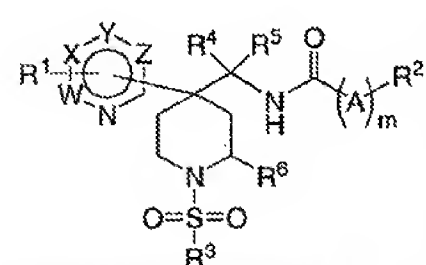


wherein m is zero **and** R² is selected from the group consisting of (1), (2) or (4) as recited by instant claim 1 **and** R³ is NOT selected from the group consisting of (1) as recited by instant claim 1.

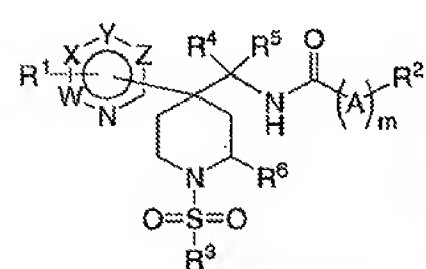
Art Unit: 1614

Group III, claim(s) 1-15 and 18-23, drawn to compounds of formula Iwherein R^2 is selected from the group consisting of

(3) or (5) as recited by instant claim 1.

Group IV, claim(s) 1-10, 12-14, 16 and 18-23, drawn to compounds of formula Iwherein m is one and A is N.**Group V**, claim(s) 1-10, 12-14 and 17-23, drawn to compounds of formula Iwherein m is one and A is O.

Art Unit: 1614

Group VI, claim(s) 1-23, drawn to compounds of formula I

that are not compounds of Groups I-V above.

Group VII, claim(s) 24, drawn to a method of using the inventions of Group I.**Group VIII**, claim(s) 24, drawn to a method of using the inventions of Group II.**Group IX**, claim(s) 24, drawn to a method of using the inventions of Group III.**Group X**, claim(s) 24, drawn to a method of using the inventions of Group IV.**Group XI**, claim(s) 24, drawn to a method of using the inventions of Group V.**Group XII**, claim(s) 24, drawn to a method of using the inventions of Group VI.**Group XIII**, claim(s) 25, drawn to a method of using the inventions of Group I.**Group XIV**, claim(s) 25, drawn to a method of using the inventions of Group II.**Group XV**, claim(s) 25, drawn to a method of using the inventions of Group III.**Group XVI**, claim(s) 25, drawn to a method of using the inventions of Group IV.**Group XVII**, claim(s) 25, drawn to a method of using the inventions of Group V.**Group XVIII**, claim(s) 25, drawn to a method of using the inventions of Group VI.**Group XIX**, claim(s) 26, drawn to a method of using the inventions of Group I.**Group XX**, claim(s) 26, drawn to a method of using the inventions of Group II.**Group XXI**, claim(s) 26, drawn to a method of using the inventions of Group III.**Group XXII**, claim(s) 26, drawn to a method of using the inventions of Group IV.

Art Unit: 1614

Group XXIII, claim(s) 26, drawn to a method of using the inventions of Group V.

Group XXIV, claim(s) 26, drawn to a method of using the inventions of Group VI.

Group XXV, claim(s) 27, drawn to a method of using the inventions of Group I.

Group XXVI, claim(s) 27, drawn to a method of using the inventions of Group II.

Group XXVII, claim(s) 27, drawn to a method of using the inventions of Group III.

Group XXVIII, claim(s) 27, drawn to a method of using the inventions of Group IV.

Group XXIX, claim(s) 27, drawn to a method of using the inventions of Group V.

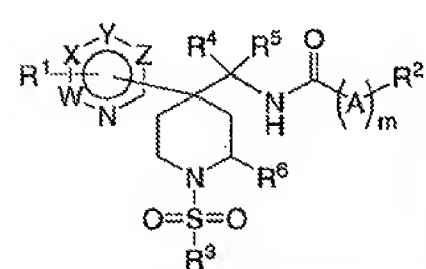
Group XXX, claim(s) 27, drawn to a method of using the inventions of Group VI.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

3. The inventions listed as Groups I-XXX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

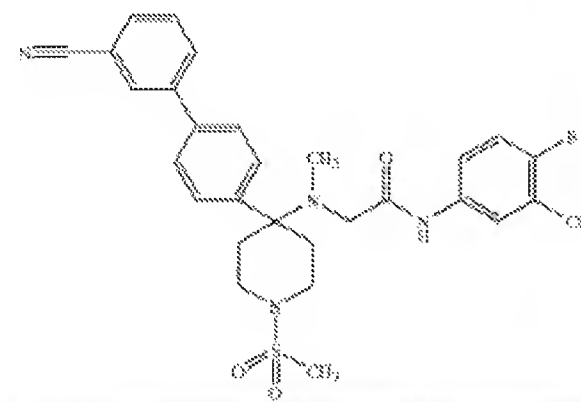
Art Unit: 1614

The special technical feature of Group IV is a compound of the formula I



wherein m is one and A is N. *Burnett et al* (US

6,664,273) teach the following compound



(Columns 53-54, First Compound)

which encompasses compounds of Group IV except that the ring containing W, X, Y and Z in the instant claims includes a N heteroatom, whereas *Burnett et al* teach compounds having no heteroatoms in said ring. It would have been obvious to substitute pyridine (as encompassed by the instant claims) with phenyl (as taught by *Burnett et al*) since the two rings are known bioisosteres as taught by *Wermuth* (The Practice of Medicinal Chemistry, Academic Press, 1996, Chapter 13, Pages 211-213) As such, Group IV does not share a special technical feature with the instant claims of Group I-XXX. Therefore, the claims are not so linked within the meaning of PCT Rule

Art Unit: 1614

13.2 so as to form a single inventive concept, and unity between Groups I-XXX is broken.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

Art Unit: 1614

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any of Groups I-XXX is elected, the following species election is required:

- A single compound species of formula (I) recited by claims 1-22;

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1-22, Applicant is required to elect a single compound species and, furthermore, as to the elected species, Applicant is required to define each of R¹-R¹¹, W, X, Y, Z and any additional variables as required for a particular species (a species for example is methyl, NOT alkyl). Additionally, as to claims 22, Applicant is required to identify the elected compound within this claim IF the elected species is recited by claim 22. Upon Applicant's election of species, the result must provide a single chemical species. The reply must also identify the claims readable on the elected species,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner: claims 2-14, 18-20 and 22 as to Group I; claims 2-14, 18 and 21-22 as to Group II; claims 2-14 and 18-22 as to Group III; claims 2-10, 12-14 and 18-22 as to Group IV and claims 2-10, 12-14 and 18-22 as to Group V. The following claim(s) are generic: claims 1 and 23 as to Group I; claims 1 and 23 as to Group II; claims 1, 15 and 23 as to Group III; claims 1, 16 and 23 as to Group IV; claims 1, 17 and 23 as to Group V; claims 1 and 23 as to Group VI; claim 24 as to Groups VII-XII; claim 25 as to Groups XIII-XVIII; claim 26 as to Groups XIX-XXIV; and claim 27 as to Groups XXV-XXX.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) each chemical species is a distinct chemical which lacks a special technical feature in view of *Burnett et al* (US 6,664,273) in view of *Wermuth* as discussed above.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

Art Unit: 1614

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614